

### **REMARKS**

Claims 1-15 and 20-21 are pending. Claims 1-15 stand rejected in the August 4, 2003, Office action under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 1-15 also stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,153,252 to Hossainy et al., in view of U.S. Patent No. 5,833,891 to Subramaniam et al.

### **Objections to the Drawings**

The drawings have been objected to under 37 C.F.R. § 1.84(p) (5). Paragraph 30 of the published application has been amended to now identify arrows 48. Thus, the issue raised in the Office action is moot as the numeral 48 has been inserted into the specification.

### **35 U.S.C. § 112 Rejection**

MPEP section 2163.07(a) provides that by disclosing in a patent application a device that inherently has a property a patent application “necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it,” and that the application may later be amended to recite the advantage without prohibited new matter. (Citations omitted). The application recites numerous metal medical devices such as stents and aneurysm coils, which may be, and often are, made from metal such as titanium. Thus, it clearly discloses metal medical devices. The Office action recognizes this fact when it asserts that “stents and coils *may* be made from metals.” Consequently, the entry of such language does not constitute new matter. Nevertheless, the issue is moot as this language has been removed from the claims, through the broadening amendments described above.

### **Examiner's Suggestions**

Claim 12 has been amended to further clarify the claimed invention and now recites “exposing the coating on the coated medical device to the supercritical fluid that has been

interfaced with the therapeutic.” The Examiner is correct that claim 12 does not require that the steps be carried out in order as they may be carried out in numerous ways. As to the other assertions and conclusions made in the Office action regarding the interpretation of this claim, the undersigned disagrees with the assertions to the extent they could be read to limit claim 12 or otherwise read limitations from the specification into the claim. Claim 12 is entitled to its broadest interpretation under the law and should not be read to include limitations from the specification. Put another way, the claim and not the specification defines what the claim claims.

### 35 U.S.C. § 103

#### Claims 1-15

Without reaching the propriety of combining the cited references, the undersigned submits that the pending claims are patentable over them because they each fail to disclose or suggest “transporting the interfaced therapeutic and supercritical fluid towards the medical device,” as in claim 1 and “exposing the coating on the coated medical device to the supercritical fluid that has been interfaced with the therapeutic” as in claim 12.

With regard to Subramaniam et al. (U.S. patent 5,833,891) the undersigned submits that the supercritical fluid in this reference is used as an anti-solvent. The title “Methods for a Particle Precipitation and Coating Using Near-Critical and Supercritical Anti-solvents,” along with numerous passages throughout the reference (*see e.g.*, Abstract, col. 5 at 2-9; and claim 1), make this clear. In other words, the supercritical fluid is used to precipitate out a drug that is dissolved in something else. Conversely, in claim 1 the therapeutic and supercritical fluid are transported together towards the medical device. This is unlike the ‘891 patent, which uses a carrier different than the supercritical fluid to move the drug. As to claim 12, the coated medical device is exposed to supercritical fluid that has been interfaced with a therapeutic. Conversely, in the ‘891 patent the supercritical fluid is not first interfaced with a therapeutic and then exposed to a coated medical device. Rather, the supercritical fluid is used to precipitate the drug from a dispersant that is not in a supercritical state.

#### Claims 20-21

Claims 7 and 9 have been rewritten in independent form. Without addressing the

propriety of the other Section 103 rejections, the undersigned submits that the Office action has not met its burden to set out a prima facie case with regard to these claims as each and every limitation must be found in the cited references. With regard to claim 7, the Office action simply says it would have been obvious without providing any support. The undersigned disagrees with this assertion and requests that support be provided by the Examiner. As to claim 9, the Office action is completely silent on this claim. Thus, it has also failed to carry its burden with regard to this rejection. Consequently, for at least these reasons, claims 20-21 are patentable over the cited references.

### **References Not Relied Upon**

As not being directly cited against the pending claims, the undersigned does not address any of the references made of record in paragraph 7 of the Office action. However, the undersigned does not acquiesce or necessarily agree with the characterizations of any of these references.

### **Declaration of Robert E. Richard**

The undersigned wishes to clarify the record with respect to paragraph 3 of Mr. Richard's Declaration. The last sentence of that paragraph should read

Reduction to practice of the claimed subject matter occurred at least by the end of 2000, as indicated by the reference in Exhibit A to a bench test in 2000 that established the invention would work for its intended purpose beyond the probability of failure.

Likewise, page 2 of the June 5, 2003, Amendment Under 37 C.F.R. § 1.116 should be read to include this change as well.

**CONCLUSION**

Reconsideration in light of the proceeding remarks is requested.

Should the Examiner have any questions regarding this submission, he is invited to contact the undersigned at 202-220-4311.

Respectfully submitted,

Dated: October 29, 2003

By: \_\_\_\_\_



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